

# EXHIBIT G

Declaration of Omar Gonzalez-Pagan in support of  
Motion to Exclude Expert Testimony of Dr. Paul W. Hruz  
*Kadel v. Folwell*, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

# Understanding Unapproved Use of Approved Drugs "Off Label"



**Exhibit  
0015**

9/29/2021  
Hruz

Has your healthcare provider ever talked to you about using an FDA-approved drug for an unapproved use (sometimes called an "off-label" use) to treat your disease or medical condition?

It is important to know that before a drug can be approved, a company must submit clinical data and other information to FDA for review. The company must show that the drug is safe and effective for its intended uses. "Safe" does not mean that the drug has no side effects. Instead, it means the FDA has determined the benefits of using the drug for a particular use outweigh the potential risks.

When you are prescribed a drug for its approved use, you can be sure:

- That FDA has conducted a careful evaluation of its benefits and risks for that use.
- The decision to use the drug is supported by strong scientific data.
- There is approved drug labeling for healthcare providers on how to use the drug safely and effectively for that use.

The approved drug labeling for healthcare providers gives key information about the drug that includes:

- The specific diseases and conditions that the drug is approved to treat.
- How to use the drug to treat those specific diseases and conditions.
- Information about the risks of the drug.
- Information that healthcare providers should discuss with patients before they take a drug.

Some drugs may also have labeling information for patients such as Medication Guides, Patient Package Inserts and Instructions for Use.

### **Why might an approved drug be used for an unapproved use?**

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.

You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition.

### **What are examples of unapproved uses of approved drugs?**

Unapproved use of an approved drug is often called "off-label" use. This term can mean that the drug is:

- Used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
- Given in a different way, such as when a drug is approved as a capsule, but it is given instead in an oral solution.
- Given in a different dose, such as when a drug is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day.

If you and your healthcare provider decide to use an approved drug for an unapproved use to treat your disease or medical condition, remember that FDA has not determined that the drug is safe and effective for the unapproved use.

### Questions you may want to consider

If your healthcare provider is thinking about using an approved drug for an unapproved use, you may want to ask your healthcare provider questions like these:

- What is the drug approved for?
- Are there other drugs or therapies that are approved to treat my disease or medical condition?
- What scientific studies are available to support the use of this drug to treat my disease or medical condition?
- Is it likely that this drug will work better to treat my disease or medical condition than using an approved treatment?
- What are the potential benefits and risks of treating my disease or medical condition with this drug?
- Will my health insurance cover treatment of my disease or medical condition with this drug?
- Are there any clinical trials studying the use of this drug for my disease or medical condition that I could enroll in?

## Resources For You

- [FDA Approved Medication Guides \(/drugs/drug-safety-and-availability/medication-guides\)](#)
- [Drugs@FDA Database \(http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm\)](http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)
- [DailyMed \(https://dailymed.nlm.nih.gov/dailymed/index.cfm\)](https://dailymed.nlm.nih.gov/dailymed/index.cfm)

